EXHIBIT 34

to

Declaration of Kenneth A. Gallo in Support of Defendant's Motion for Reconsideration or, in the Alternative, for Certification of an Interlocutory Appeal

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Doc 3

TO: Kevin May Restore Robotics
Cliff Parker Restore Robotics

FROM: Ron Arkin

DATE: April 9, 2019

Re: Discussions with FDA about EndoWrist counter

RESTORE ROBOTICS
Los Angeles | Chicago

ACG was charged to learn if a) Restore Robotics was required to have a 510(k) as their customers and potential customers claim and b) does modifying the OEM counter cause the multi-use device to change classifications.

The Intuitive Medical developed the Da Vinci™ Surgical System. It is a surgical robot which is controlled by the actions of a physician. The Da Vinci™ Surgical robot has 3 surgical accessory arms, a camera, and a physician console. The Surgical accessory arms have controllable surgical arms ("Wrists").

Restore Robotics provides the ability to reset the use counter, extending the life of the instrument. The service process involves a complete evaluation, repair, and testing of the instrument, including the distal/tool end.

Assessment

Called FDA and was not able to reach Dr. Chen of the ODE staff. Another team member called me for him. The situation was explained, and it was decided that a *PRESUBMISSION MEETING* should be sent for a real evaluation.

05/15/19

Phone call with Kevin

Going to meet with MEDLINE in Chicago. Advised to watch out. Claims they told them everything about their business and seeking regulatory advice. Spent the last 3 weeks getting a firm to teach them how to efficiently repair/clean devices to help their throughput. Did not do anything regarding Pre-Sub. Discussed about the presub and Kevin will check with Josh on whether to pursue or not.

MEMORANDUM

The Endowrist is the issue because Restore Robotics wants to reset the counter which then changes the device original specifications. To get FDA to accept this, they will need to

Learn what the DaVinci specs are for each device

a) Develop a robust protocol that would prove that the device can withstand uses greater than those specified by the manufacturer.
b) Implement said protocol